Clinical Edit Criteria

Drug/Drug Class: **Non-Sedating Antihistamines**

Prepared by: Missouri Medicaid

☐ **New Criteria** ☒ **Revision of Existing Criteria**

Executive Summary

Purpose: Reduce drug cost by initially limiting prescribing to one preferred non-sedating antihistamine product.

Why was this Issue Selected: For previous reporting period (August 2001-July 2002), Missouri Medicaid paid $21,360,079 for non-sedating antihistamines. This represents 2.73% of total drug spend

Program Specific Information:

Total Scripts in Drug Class	Projected Savings in Drug Class
265, 398	**$1,376,413**

Reference Drug/Drugs With No Clinical Edit Imposed:

Trade Name	Generic Name
Claritin	Loratadine
Claritin-D 24 Hour	Loratadine/P-ephed
Claritin-D 12 Hour	Loratadine/P-ephed
Alavert	Loratadine

Drugs Which Will Be Affected By Clinical Edits:

Trade Name	Generic Name
Zyrtec	Cetirizine
Zyrtec-D	Cetirizine/P-ephed
Clarinex	Desoratadine
Clarinex Dissolve Tabs	Desoratadine
Allegra	Fexofenadine
Allegra-D	Fexofenadine/P-ephed

Setting and Population: All patients taking non-sedating antihistamines other than the reference drug(s).

Type of Criteria:

☐ Increased risk of ADE ☐ Non-preferred agent

☐ Appropriate Indications

Purpose of Clinical Edit Criteria

While prescription expenditures are increasing at double-digit rates, payors are also evaluating ways to control these costs by influencing prescriber behavior and guide appropriate medication usage. Clinical Edit criteria assist in the achievement of qualitative and economic goals related to health care resource utilization. Restricting the use of certain medications can reduce costs by requiring documentation of appropriate indications for use, and where appropriate, encourage the use of less expensive agents within a drug class. Clinical Edit criteria can also reduce the risk of adverse events associated with medications by identifying patients at increased risk due to diseases or medical conditions, or those in need of dosing modifications.

Why has this Clinical Issue Been Selected for Review

The second generation of antihistamines, termed non-sedating antihistamines, were developed principally to avoid sedative actions. As a group these drugs are reversible, peripherally selective, competitive H_1 receptor antagonists, that reduce or prevent most of the physiologic effects that histamine normally induces at the H_1 receptor site.[1] They do not prevent histamine release, nor bind with histamine that has already been released. Antihistaminic effects include: inhibition of respiratory, vascular, and GI smooth muscle constriction; decreased capillary permeability, which reduces the wheal, flare, and itch response; and decreased histamine-activated salivary and lacrimal secretions.[1] Antihistamines can also potentiate the drying effect by suppressing cholinergically innervated exocrine glands.[3] These drugs are shown to be clinically significant in treating patients with seasonal and perennial allergic rhinitis, as well as chronic idiopathic urticaria. Allergic rhinitis is an inflammatory disease of the nasal mucosal membranes that causes sneezing, rhinorrhea, nasal puritis, and congestion.[4] Patients that have seasonal rhinitis (hay fever) exhibit symptoms at specific times of the year, while patients who have perennial rhinitis have symptoms all year. [4]

Of the non-sedating antihistamines, Loratadine is the most cost effective agent for use in the Missouri Medicaid Pharmacy Program. It=s side effect profile, as well as available medical and clinical information, exceeds or is comparable to other drug choices within the same therapeutic class.

	Dose	Interval	Sedative Effects	Antihistaminic Activity	Anticholinergic Activity
loratadine	10 mg	q 24 h	low to none	high to very high	low to none
fexofinadine	60 mg	q 12 h	low to none	no data	low to none
cetirizine	5-10 mg	q 24 h	low to none	high to very high	low to none
desloratadine	5 mg	q 24 h	see loratadine historically specific data not available	see loratidine historically specific data not available	see loratadine historically specific data not available

Setting and Population

All patients taking non-sedating antihistamines other than the reference drug(s).

Override Approval Criteria

Reference Drug Product: Loratidine

- Drug Class for review: Non-sedating antihistamines
- Documented ADE to Loratadine (Claritin)
- Documented failure on Loratadine (Claritin) therapy in last 12 months
- Demonstrates therapy compliance on non-reference product.
- Claims for Zyrtec Syrup for patient's 2 years of age and younger

Override Denial Criteria

- No initial 14 day trial period on reference drug (s)
- Lack of adequate compliance during trial period

Disposition of Edit

- **Denial:** Exception 681 "Step Therapy"

Required Documentation

- progress notes
- medwatch form

References

1. Facts and Comparisons7, p.699, 2002.
2. Facts and Comparisons7, p. 706-07, 2002.
3. USPDI7, Micromedex, 2002.
4. American Family Physician, AAFP. A Overview of Methods for Treating Allergic Rhinitis.@ January 2000.